IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF VIRGINIA

WHOLE WOMAN'S HEALTH ALLIANCE, *et al.*, Plaintiffs, v. UNITED STATES FOOD AND DRUG ADMINISTRATION, *et al.*, Defendants.	Case No. 3:23-cv-00019 Honorable Robert Ballou

[PROPOSED] ORDER GRANTING PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT

This matter comes before the Court on Plaintiffs' Motion for Summary Judgment. Having considered the motion, Defendants' cross motion for summary judgment, and any oppositions, replies, and oral argument presented, it is HEREBY ORDERED, ADJUDGED, AND DECREED that Plaintiffs' motion for summary judgment of the first and second causes of action in their Complaint is GRANTED.

The Court HEREBY DECLARES, pursuant to 28 U.S.C. § 2201, that the 2023 Mifepristone REMS in its entirety violates the Administrative Procedure Act ("APA"), as it both (i) exceeds FDA's statutory authority and limitations and (ii) is and arbitrary and capricious; and

The Court DECLARES, pursuant to 28 U.S.C. § 2201, that ETASU A (Prescriber Certification), ETASU B (Pharmacy Certification), and ETASU D (Patient Agreement Form) violate the APA, as they both (i) exceed FDA's statutory authority and limitations and (ii) are arbitrary and capricious;

[The Court VACATES the 2023 Mifepristone REMS in its entirety while maintaining the approvals of the brand name Mifeprex (mifepristone), NDA 020687, and the generic mifepristone, ANDA 091178;]

[The Court REMANDS this matter to the United States Food and Drug Administration ("FDA") and ORDERS FDA to reevaluate the 2023 Mifepristone REMS while maintaining the approvals of the brand name Mifeprex (mifepristone), NDA 020687, and the generic mifepristone, ANDA 091178;

The Court ORDERS that FDA's forthcoming review must weigh each of the statutory factors for REMS and ETASU set out at 21 U.S.C. § 355-1(a)(1), (f)(1)-(2), and (g)(4)(B);

The Court ORDERS FDA to consider and address the following materials to the extent that they are already part of the administrative record in this case, are identified by FDA during its forthcoming literature review, or are submitted to FDA by Plaintiffs or by third parties during the course of its forthcoming review:

a. Policy statements, opinions, commentary, letters, and citizen petitions relating to the mifepristone REMS, and the references cited therein, submitted and/or issued by professional medical societies whose members include practitioners who routinely prescribe or dispense mifepristone for abortion care or would prescribe or dispense mifepristone for abortion care if the REMS were removed;

b. The Schummers *et al*. study, 2022 CP 99–109, and comparable relevant safety data;

c. Quantitative and qualitative studies, reports, and testimonials by stakeholders (e.g., physicians, advanced practice clinicians, and pharmacists who currently prescribe or dispense mifepristone, or who seek to do so) relevant to whether the REMS and ETASU satisfy the statutory requirements of 21 U.S.C. § 355-1(a)(1), (f)(1)-(2), and (g)(4)(B);

d. Data reflecting whether and how mifepristone patients "have difficulty accessing health care," *id.* §355-1(f)(2)(C)(ii);

e. Evidence regarding whether the three mifepristone ETASU "conform with [ETASU] for other drugs with similar, serious risks," *id.* §355-1(f)(2)(D)(i); and

The Court ORDERS FDA to provide periodic reports to the Court as to the status of its mifepristone REMS review and anticipated timeframe for completion;]

The Court awards costs, expenses, and reasonable attorneys' fees to Plaintiffs, pursuant to 28 U.S.C. § 2412; and

It is FURTHER ORDERED that Defendants' motion for summary judgment is DENIED.

DATED this ____ day of _____, 20 ____.

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United States District Judge